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510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

K020214

FEB 2 6 2002

NAME OF FIRM: Finsbury (Instruments) Limited
13 Mole Business Park
Randalls Road
Leatherhead, Surrey KT22 OBA
United Kingdom

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Medial Rotation Knee™ System

COMMON NAME: Knee Prosthesis

CLASSIFICATION: Prosthesis, Knee patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer per 21CFR, Sec 888.3390

DEVICE PRODUCT CODE: 87JWH

SUBSTANTIALLY EQUIVALENT:
DePuy, Freeman/Samuelson Total Knee (K830726)
Sulzermedica, Mark II Freeman/Samuelson Total Knee System (K853730)
Biomet, Freeman/Samuleson Total Knee System (K943025)
Wright Medical Technology, Inc., Advance Ultra-Conguent Tibial Insert (K972770)
Renaissance Instruments, LLC., FS 1000 Knee System (K991052)

DEVICE DESCRIPTION: The Medial Rotation Knee™ System is both a primary and revision total knee system composed of a CoCr Femoral component mating with a stemmed CoCr metal backed polyethylene Tibial and all-poly Patella components. The conguency in tibialfemoral and patellafemoral articulation allow for natural knee movement and ROM while minimizing polyethelene wear.

INTENDED USE: The Medial Rotation Knee™ System is intended for single-use cemented implantation for use in total knee arthroplasty surgery for the reduction in relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease resulting from osteoarthritis, traumatic arthritis, or avascular necrosis
- Inflammatory degenerative joint disease including rheumatoid arthritis
- Correction of varus, valgus, or post traumatic deformity
- Correction or revision of unsuccessful osteotomy or arthrodesis
- Revision procedures where other treatments or devices have failed
- Treatment of fractures that are unmanageable using other techniques

BASIS OF SUBSTANTIAL EQUIVALENCY: The Medial Rotation Knee™ System is substantially equivalent to the many semi-constrained metal/polyethylene total knee systems currently on the market and specifically to the:
(1). FS 1000 Knee System from Renaissance Instruments, LLC.,
(2). Advance Ultra-Congruent Tibial Insert from Wright Medical Technology, Inc, and
(3). Freeman/Samuelson Total Knee System from Biomet, Inc.

SUMMARY OF SAFETY AND EFFECTIVENESS: The Medial Rotation Knee™ System is shown to be safe and effective with over 30 years of proven clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Finsbury (Instruments) Limited
c/o Mr. Al Lippincott
U.S. Regulatory Representative
Engineering Consulting Services, Inc
3150 E. 200th St
Prior Lake, Minnesota 55372

Re: K020214
Trade Name: Medial Rotation Knee System
Regulation Number: 888.3390
Regulation Name: Knee patellofemorotbibial polymer/metal/polymer semiconstrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: January 19, 2002
Received: January 22, 2002

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FINSBURY
INSTRUMENTS

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Surrey KT22 OBA
Tel: 01272 360830
Fax: 01372 360779
email: mail@finsbury.org

510(k) NUMBER: K020214

DEVICE NAME: Medial Rotation Knee™ System

INDICATIONS FOR USE:

The Medial Rotation Knee™ System is intended for single-use 'cemented' implantation for use in a total knee arthroplasty surgery for the reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease resulting from osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of varus, valgus, or post traumatic deformity;
- Correction or revision of unsuccessful osteotomy or arthrodesis;
- Revision procedures where other treatments or devices have failed;
- Treatment of fractures that are unmanageable using other techniques;

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Gen... and Neuro...

510(k) K020214

Prescription Use X OR Over-The-Counter-Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Registered Office:
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Leatherhead Surrey KT22 OBA United
Kingdom

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